

Remarks/Arguments

Claims 1 and 14-16 are pending and are presented for further prosecution.

Claim 1 has been amended.

Claim 1, previously allowed, has been rejected as have Claims 14-16, under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, the Examiner contends that use of the terms "substantially" and "preferentially" in Claims 1 and 14 make the claims indefinite. The Examiner rejects Claims 15-16 as depending from rejected Claim 14. However, Claims 1 and 14-16 would be considered allowable if rewritten or amended to overcome the indefiniteness rejection.

Applicants respectfully traverse the Examiner's rejection and request reconsideration in view of the remarks that follow.

In reviewing and considering the definiteness of claim language for compliance with 35 U.S.C. § 112, second paragraph, an Examiner must analyze the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope in light of the specification and prior art. The fact that claim language, including terms of degree, may not be precise does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984).

The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. See, e.g., *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960); *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975)(the court held that the limitation which produces "substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal."). Like the term "about," the term "substantially" is a descriptive term commonly used in patent claims to "avoid a strict numerical boundary to the specified parameter." *Pall Corp. v. Micron Seps.*, 66 F. 3d 1211, 1217, 36 USPQ2d 1225, 1229 (Fed. Cir. 1995).

In this case, the term "substantially" is used to describe the degree of moisture impermeability of the product packaging. The specification at Paragraph [0033] explains the meaning and standard for measuring moisture impermeability. When the

specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). The use of the term "substantially" does not render the phrase "substantially moisture impermeable" so unclear and indefinite such that there is no means by which to ascertain the claim scope. One of ordinary skill in the art, in view of Paragraph [0033] is apprised of the scope of the claims at issue. Therefore, the review of the claim in its entirety serves the notice function required by 35 U.S.C. § 112, second paragraph. See, e.g., *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F. 2d 819, 821-22, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988)(the court noting that terms such as "approach each other," "close to," "substantially equal," and "closely approximate" are ubiquitously used in patent claims and that such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts); See also, *Ecolab, Inc. v. Envirochem, Inc.*,(Fed. Cir. 2001), where the court held that the district court erred as to the proper construction of the phrase "substantially uniform"; not giving the phrase its ordinary and accustomed meaning.

Applicants, however, have amended line 6 of Claim 1 by deleting the words "substantially moisture impermeable" as being redundant since Paragraph [0033] makes it clear that the product package is defined broadly, and the cover sheet is simply an embodiment of and part of the product package. See Paragraph [0055].

The term "preferentially" like the term "substantially" is a descriptive term used ubiquitously and serving reasonably to describe the claimed subject matter to those of ordinary skill in the art. In this case, the term "preferentially" describes the moisture permeability of the packaging material of the pouch that holds the transdermal drug delivery system when compared to other non-water components or drug making up the transdermal system. Again, the Specification states the meaning that the terms in the claim are intended to have. As described in Paragraph [0045] of the specification, the pouch is made of material that is moisture permeable but not significantly permeable to non-water components or drug making up the transdermal system based upon the moisture vapor transmission rate requirements specifically set forth in that paragraph.

The use of the term "preferentially" in this context does not render the phrase "preferentially permeable to moisture" so unclear and indefinite such that there is no means by which to ascertain the scope of Claims 1 and 14.

Since Applicants submit that the rejection of Claim 14 has been overcome, the rejection of Claims 15-16 which depend therefrom has also been overcome.

Applicants respectfully request the Examiner for favorable reconsideration of the application. Applicants believe that the application is now in condition for allowance.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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By: Jay Q Kolman  
Jay Q Kolman  
Registration No. 43,727  
Attorney for Applicants

Customer No. 30527  
Noven Pharmaceuticals, Inc.  
11960 S.W. 144 Street  
Miami, FL 33186  
Telephone: (305) 253-5099  
Facsimile: (305) 251-1887  
E-mail: [jkolman@noven.com](mailto:jkolman@noven.com)